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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,646	12/07/2001	Peter W. Bringmann	BERLX 87	7678

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NEIL G. MIYAMOTO
BERLEX BIOSCIENCES
2600 HILLTOP DRIVE
P.O. BOX 4099
RICHMOND, CA 94804-0099

EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,646	BRINGMANN ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *1-35,42-68 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-41 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *030702*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-35, 42-68 and 70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed 31 October 2003. Claims 36-41 and 69 also include non-elected inventions (methods of treating spinal cord damage or trauma, neuronal tissue damage, Huntington's disease, myelopathy, myelitis, and syringomyelia). These methods are also withdrawn from consideration and the claims should be amended to claim only the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities: the arrangement of the specification does not follow the above guidelines. Specifically, the Brief Description of the Drawings is found at page 32 of the specification, and it would be more appropriately placed earlier in the application. This is a concern because the specification makes reference to the Figures before the Description of the Drawings has been presented. This is confusing.

Appropriate correction is required.

The abstract of the disclosure is objected to because it does not relate to the claimed invention. Correction is required. See MPEP § 608.01(b).

Sequence Compliance

The specification is objected to for failure to comply with the Sequence Rules (MPEP 2422).

1. The specification makes multiple references to amino acid sequences without referencing the sequence identifier for the recited sequence. See 37 CFR 1.821(d) which requires use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text. See page 2, lines 29-30, page 7, line 5, page 9, lines 15-16, page 10, line 26, etc.

2. The specification contains amino acid sequences which are not represented by a sequence identifier (see page 4, lines 5-6). It is not clear if these sequences are part of a larger sequence already present in the Sequence Listing, or if a new Sequence Listing will be required to include these sequences. If these are part of a larger sequence, then the sequence identifier along with the position numbers of the fragment should be included following the recitation of the amino acid sequence. See 37 CFR 1.821 (a)-(d). If a new Sequence Listing is required, Applicant will need to provide a new computer readable form, a new paper copy and a statement indicating that the paper copy and computer readable form are the same and include no new matter.

Claim Objections

Claims 40-41 are objected to because of the following informalities: failure to comply with 37 CFR 1.821 (d). Use of a sequence identifier is required. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36-41 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (Multiple Sclerosis 3: 113-120, 1997) in view of Nakamura et al. (Glia 28: 53-65, 1999.).

Webster teaches that growth factors, including fibroblast growth factor, are involved in the proliferation, differentiation and survival of cells in the oligodendroglial lineage. Oligodendroglia are the cells that form and maintain myelin sheaths. In multiple sclerosis, an autoimmune response occurs in which there is inflammatory demyelination in central nervous system white matter. Webster teaches that administration of growth factors could increase proliferation of progenitor oligodendrocytes, enhance their differentiation, upregulate synthesis of myelin constitutents and promote myelin regeneration in the adult CNS, which would be beneficial for treatment of MS (see page 114, column 1). Webster does not teach or suggest the administration of FGF-9 for the treatment of multiple sclerosis (MS).

Nakamura et al. teach a number of biological activities for FGF-9. Included in these are the ability to promote proliferation of primary cortical astrocytes, oligodendrocyte type 2 astrocyte progenitor cells, fibroblasts and neuron-like PC-12 cells. FGF-9 also has a trophic effect on cultured motor neurons (see page 54, column

1). Nakamura et al. further teach the expression of FGF-9 in astrocytes in spinal cord, oligodendrocytes in cerebellar white matter and corpus callosum (see page 61, column 2). Therefore, Nakamura et al. concludes that FGF-9 is involved in neural development, providing trophic support to neurons, proliferation and activation of astrocytes, proliferation and differentiation of oligodendrocytes, and repair of CNS injury.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention to administer the FGF-9 of Nakamura et al. for the treatment of MS because Webster teaches that growth factors would be useful for treatment of MS if they had biological activities such as the ability to increase proliferation and differentiation of oligodendrocytes, upregulate synthesis of myelin constitutents, and promote myelin regeneration in the CNS. Since FGF-9 possesses some of these biological activities, it's administration for the treatment of MS would be advantageous and beneficial, as suggested by Webster for growth factors in general. One of ordinary skill in the art would be motivated to administer FGF-9 for the treatment of MS because Nakamura et al. teach that FGF-9 is expressed in the cells of the CNS which are involved in myelination, that the receptors for FGF-9 are present and that FGF-9 stimulates cellular processes which are involved in myelin formation. Therefore, the invention as a whole would have been *prima facie* obvious at the time it was made, absent evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud